REMARKS

In the Action, claims 1-20 are rejected. In response, claims 12 and 16 are amended to correct the matters of form noted on page 2 of the Action. In view of these amendments and the following comments, reconsideration and allowance are requested.

The Rejections

Claims 1, 2, 7, 12, 13-15 and 17-20 are rejected under 35 U.S.C. § 103(a) as being obvious over DE 29922585 and WO 02/083194 to Beam et al.

DE '585 and WO /194 either alone or in combination do not suggest the claimed bone formation agent comprising sintered particles of calcium phosphate having the pore distribution and interconnecting pore as defined in claim 1. DE '585 is cited on page 2 of the present specification. DE '585 does not disclose or suggest a bone formation agent. DE '585 relates to a temporary bone defect filler. There is no suggestion of a bone formation agent or a bone formation agent having an absence of interconnecting macropores as in the present invention. The present invention is specifically directed to a bone formation agent having a porosity and sintering design without interconnecting macroporosity. See, for example, page 8, third paragraph of the specification.

Claim 1 specifically recites a bone formation agent having sintered particles of calcium phosphate with a porosity formed by two discrete pore size distributions and where the sintered particles of the calcium phosphate have a particle size smaller than 63 μm and interconnecting pores between the particles having a pore size less than 10 μm. Thus, the claimed invention is directed to a bone formation agent that does not have interconnecting macropores as in DE '585. DE '585 refers to a bone defect filler having interconnecting macropores with an average size in the range of 50 to 1,000 μm. See, for example, page 6, lines 1 and 2 of the English translation.

Moreover, DE '585 explicitly teaches that the interconnecting macropores are favorable to promote rapid boney ingrowth of the implant as disclosed on page 4, lines 2 and 3. Thus, DE '585 does not suggest a bone formation agent having interconnecting pores between the sintered particles with a pore size of less than 10 μm. As disclosed on page 7, second paragraph of the present specification, microporosity is understood by those skilled in the art to refer to pore size distributions of less than 10 μm. Macroporosity refers to pore sizes above 100 μm. Macroporous bone regeneration agents have a large macropore component, which results in weak mechanical stability of the sintered particles.

The temporary bone defect filler of DE '585 differs significantly from the claimed bone formation agent and does not provide the advantages of the claimed bone formation agent. DE '585 does not disclose or suggest to one skilled in the art the features of the claimed invention and provides no motivation to one skilled in the art to modify the teachings of the prior art to obtain the claimed invention.

In contrast to the present invention, DE '585 specifically teaches the importance of interconnecting macropores, and thus, effectively teaches away from the claimed invention. The interconnecting micropores of less than 10 μm would not be effective in the product of DE '585 because the micropores will not promote the rapid boney growth desired by DE '585. Therefore, it would not have been obvious to one skilled in the art to replace the macropores of DE '585 with micropores as in the claimed invention. In the claimed invention, an interconnecting macropore network is eliminated as disclosed on page 3, third paragraph of the present specification. Claim 1 specifically defines the interconnecting pores having a pore size of less than 10 μm. Page 6, lines 1 and 2 of DE '585 specifically disclose the interconnecting macropores with an average size of 50 to 1,000 μm which makeup 50 to 90% of the total porosity. Each of the Examples of DE '585 produce a body having at least 30% by volume of macropores with an average size of 500 μm.

The pore size distribution and particle size of the bone formation agent of the present invention are demonstrate throughout the specification. The bone formation agent of the present invention has improved mechanical strength as disclosed on page 9, third paragraph, due to the lack of interconnecting macropores. The absence of macropores of the present invention prevent the interior of the bone formation agent from being colonized by germs or microorganisms which can otherwise elude systemic treatment with antibiotics.

WO '194 is sufficiently different from the present invention and the filler of DE '585 that it would not have been obvious to one skilled in the art to modify the filler of DE '585 according to WO '194. Furthermore, it would not be technically possible to modify the process of DE '585 or the resulting product according to WO '194 to achieve an isotropic structure. WO '194 does not disclose granulates or shaped articles formed from granulates having a statistically distributed porosity with the discrete pore size ranges of the present invention. The present invention is directed to granulates or shaped pieces formed from the granulates having a statistical pore size distribution, polygonal formed pores as well as polygonal formed granulates. WO '194 relates to a regular biostructure referred to as an engineered shaped article.

WO '194 does not disclose discrete pore size ranges of the claimed invention. As recited in claim 1, the interconnecting pore share of the porosity of the particles has a pore size less than 10 μm. The porosity has an irregular geometric shape where the sintered particles of calcium phosphate have a particle size smaller than 63 μm and a d_{50} value in the range of 5 to 20 μm. WO '194 does not suggest sintered particles of calcium phosphate having the claimed particle size. Therefore, it would not have been obvious to one of ordinary skill in the art to combine the teachings of WO '194 with DE '585. Even if one were to do so, the resulting combination would not be the claimed invention.

DE '585 and WO '194 do not disclose or suggest the pore size distribution having pore diameters in the range of 0.5 to 10 μm and a second pore diameter of 10 to 100 μm as in claim 2, and where the particles have interconnecting pores with a pore size of less than 10 μm as in claim 2. WO '194 only discloses pore sizes being greater than 10 μm. WO '194 and DE '585 do not disclose the claimed two discrete pore size distributions of claim 2.

DE '585 does not disclose a granulate having a particle size in the range of 50 to 10,000 μm as in claim 7, the pore size distribution of claim 12, the shaped body of claim 13, the statistical porosity of claim 14, or the tubular porosity of claim 15, in combination with the features of claim 1. DE '585 and WO '194 also do not disclose the additives of claim 17, the shape of the bone formation agent of claim 18, the dimensions of claim 19, or the structures of claim 20, in combination with the features of claim 1. Accordingly, the claims are not obvious over the combination of DE '585 and WO '194.

Claims 3, 4, 11, 12 and 16 are rejected under 35 U.S.C. § 103(a) as being obvious over DE '585, WO '194 and further in view of WO 92/21302. WO '302 is cited for disclosing an implant made of a porous material having three distinct pore sizes.

WO '302 specifically discloses the pores being distributed in different parts of the implant. WO '302 does not disclose three distinct pore sizes in the particles as in the claimed invention. WO '302 further fails to suggest the three discrete pore size distributions having pore diameters in the range of 0.5 to 10 μm, 10 to 100 μm and 100 to 5,000 μm where the particles have interconnecting pores limited to less than 10 μm. It would not have been obvious to one of ordinary skill in the art to provide the bone formation with the claimed discrete pore size distribution of the present invention in view of WO '302, WO '194 and DE '585.

The combination of the cited patents does not suggest the pore size distribution of claim 3, the pore size distribution having 0.5 to 10 μm and 5 to 40% by volume and a pore

size distribution with a pore diameter of 10 to 100 μm and 1 to 40% by volume of a pore size distribution with pore diameters of 100 to 5,000 μm with an overall porosity not exceeding 85% by volume as in claim 4. The claimed pore size distribution is an important aspect of the invention which is not disclosed or suggested in the cited art. WO '302 specifically discloses "not more than 5%" of the pore size being in the range of 10 to 50 μm. The micropores having a pore size of less than 10 μm connect the other two pore distributions in the present invention. The claimed pore size distribution having a pore diameter in the range of 0.5 to 10 μm define the interconnecting pore system. See, for example, page 9, third paragraph of the specification which discloses the interconnecting pore network having an upper limit of 10 μm. Thus, it is essential for the invention that the proportion of the interconnected pores be less than 10 μm.

The combination of the cited patents also does not disclose the maxima of the discrete pore size distribution of claims 11 and 12 or the pore size distributions of claim 16, in combination with the features of claim 1. Accordingly, the claims are not obvious over the combination of the cited patents.

Claims 5, 8-10 and 18-20 are rejected under 35 U.S.C. § 103(a) as being obvious over DE '585, WO '194, WO '302 and further in view of U.S. Patent No. 6,521,246 to Sapieszko et al. Sapieszko et al. is cited for disclosing inorganic shaped bodies for bone grafting.

Sapieszko et al. is directed to inorganic shaped bodies from beta-tricalcium phosphate having a porosity of 30 to 90%. The pores are disclosed as being uniform and being produced according to a template technique using a sponge as a substrate. The sponge of Sapieszko et al. is imbibed with a reaction solution containing calcium phosphate. The organic portion of the sponge is burned to leave the calcium phosphate framework in the form of the sponge. The pores of the sponge normally have round shapes as shown in the Figures.

Sapieszko et al. does not suggest to one of ordinary skill in the art the calcium phosphate containing 95% of alpha-tricalcium phosphate, beta-tricalcium phosphate, octacalcium phosphate, alkali metal-modified and/or alkaline earth metal-modified tricalcium phosphate, calcium diphosphate, carbonate apatite of type B, calcium-deficient hydroxyapatite or mixtures thereof as in claim 5, in combination with the features of claim 1. Sapieszko et al. also does not disclose the geometric shapes of claims 8-10, the discrete pore size distributions of claims 11 and 12, the shaped body of claims 13-15 or the pore size distribution of claim 16, either alone or in combination with the features of claim 1. Sapieszko et al. further fails to disclose the shaped body of claims 18-20 in combination with the features of claim 1.

Accordingly, claims 5, 8-16 and 18-20 are not obvious over the combination of the cited patents.

Claim 6 is rejected as being obvious over DE '585, WO '194, WO '302, Sapieszko et al. and further in view of the article by Trisi et al. Trisi et al. is cited for disclosing a pure phase beta-tricalcium phosphate. Trisi et al. provides no suggestion or motivation to one skilled in the art to use a beta-tricalcium phosphate having a phase purity of greater than 99% by weight in the bone formation of claim 1. Accordingly, claims 6 is not obvious over the combination of the cited patents.

In view of these amendments and the above comments, reconsideration and allowance are requested.

Respectfully submitted,

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